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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,010	BAMDAD, CYNTHIA C.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,13,14,17,27 and 57-62* is/are pending in the application.

4a) Of the above claim(s) *27 and 57-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 13, 14, 17, 27 and 57-62 are all the pending claims for this application.

Election/Restrictions

2. Applicant's election with traverse of Claims 1-6, 13, 14 and 17 (Group I) as to Claim 27 (Group II) in the reply filed on 11/16/07 is acknowledged. The traversal is on the ground(s) that Claim 27 is drawn to the method for making an antibody. This is not found persuasive for the reasons set forth in the Office Action of 8/22/07 and again because the antibody of Group I can be made by a materially different method than the method of Group II.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 27 (Group II) is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/16/07.

4. Claims 57-62 (Group III) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/07.

5. Claims 1-6, 13, 14 and 17 are all the pending claims under examination.

Priority

6. The priority claim to U.S. Provisional Application No. 60/498,260 (filed 8/26/03) for an antibody that binds to the MGFR/PSMGFR domain of MUC1 protein is acknowledged.

Information Disclosure Statement

7. The U.S. patent and PGPub references cited in the IDS of 2/27/06 have been considered. These references have been initialed by the Examiner on the attached 1449 form.

However, the information disclosure statement filed 2/27/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Those portions of the 2/27/06 1449 form listing these references have been stricken. Should Applicants wish to submit copies of these references in their reply, they are welcome to do so. Otherwise, should the instant application issue into a patent then none of these references would be cited in the cover page of the published patent.

Drawings

8. The replacement drawing sheets for Figures 1-28 received on 2/27/06 have been entered.

Specification

9. The use of the trademark Polyquick™, for example, has been noted in this application. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are advised to carefully check the entire specification for any other improperly identified trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-6, 13, 14 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-6, 13, 14 and 17 are directed to an antibody or antigen-binding fragment thereof. The claims read on any antibody or antigen-binding fragment that is found in nature. Products of nature do not constitute patentable subject matter as defined in 35 USC 101. See MPEP 2105. Since an antibody and an antigen-binding fragment do not exist in nature in purified form, it is suggested that Applicant use the

language "isolated" or "purified" in connection with the antibody and or antigen-binding fragment thereof to identify a product that is found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-6, 13, 14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1-6, 13, 14 and 17 are indefinite for the recitation "MGFR" in Claim 1 because it is unclear if the term represents a peptide comprising these amino acid residues or is an abbreviation for an art known molecule or domain thereof. Similarly, Claims 4-6 in depending from Claim 1 and for further reciting "PSMGFR" in Claim 4 are rejected for the same reasons.

The specification teaches on p. 12, lines 6-7 "the MGFR region of MUC1 is that extracellular portion that is closest to the cell surface and is defined by most or all of the PSMGFR." Otherwise, Figure 1 of the protein only shows a single domain referred to as "PSMGFR" which comprises SEQ ID NO:36 (p. 15, lines 1-2 of the specification). What are the functional and structural differences if any between the "MGFR" and the "PSMGFR" of MUC1?

b) Claims 5 and 6 are indefinite for the recitation "sequence set forth in SEQ ID NO: 36 or a functional variant or fragment thereof" in both claims because it is not clear if the "fragment thereof" refers to the sequence of SEQ ID NO:36 or the functional variant or both. Clarification is requested.

c) Claims 5 and 6 are indefinite because the claims recite broadening limitations for the PSMGFR of Claim 4. The specification defines PSMGFR as the sequence of SEQ ID NO:36 and claim 4 requires the antibody to bind to "PSMGFR". Claim 4 does not recite open language for the shape, form or sequence of the antibody binding target, or at least as "PSMGFR" is defined by the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

12. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5 and 6 encompass a genus of antibodies that bind to immunogenic peptide sequences that were not disclosed in the specification as originally filed. One of skill in the art could reasonably conclude that Applicants were not in possession of the

full scope of antibodies binding to peptides of SEQ ID NO:36, a functional variant or a fragment thereof comprising up to 15 amino acid additions or deletions at the N-terminus and comprising up to 20 amino acid substitutions (Claim 5) or the peptide of SEQ ID NO:36 or a functional variant or fragment thereof comprising up to 10 amino acid substitutions (Claim 6). All of the peptides encompassed by the instant claim scope would have been required to be immunogenic insofar as their capability of producing a specific antibody and where the antibody or fragment thereof was **also** required to specifically bind the MGFR domain (Claim 1) and the PSMGFR domain (Claim 4) of Muc-1.

The modifications encompassed by the claims are not restricted to any one particular amino acid within the peptide structure that can be added, deleted or substituted or to the kind of amino acid for any given substitution. Thus for any given substitution alone, there would be a possibility of 23 amino acids. The total number of modifications to the peptide is quite large and it is not readily apparent that the specification supports that many possible modifications to create a peptide which is immunogenic for an antibody ***and*** where the same antibody can also bind the MGFR domain and the PSMGFR domain of MUC-1.

The specification discloses making polyclonal rabbit antibodies against the variant peptide disclosed in SEQ ID NO:7 (shown on p. 112, at line 27 of the specification; Example 8 and 9). The specification does not disclose any other variant peptides that are a) immunogenic for producing an antibody and b) where the antibody

produced against the variant peptide also binds the native MGFR domain and the native PSMGFR domain of Mic-1.

A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. " See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.).

It has been well known that minor structural differences even among structurally related compounds can result in substantially different biology and activities. Based on the instant disclosure one of skill in the art would not know which amino acid residues or in which portion of the peptide of SEQ ID NO: 36 the amino acids are essential, which amino acids are non-essential and what particular additions, deletions and substitutions are encompassed by the claimed specificity. For example, there is insufficient guidance based on the reliance of disclosure of SEQ ID NO:36 to direct a person of skill in the art to select or to predict particular amino acids as essential for identifying immunogenic peptides encompassed by the claimed specificities. Mere idea of function is insufficient for written description; isolation and characterization at a minimum are required.

Skolnick et al (Trends in Biotechnology, 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based on sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to function of the structurally related protein (see in particular "Abstract" and Box 2).

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al,

Journal of Cell Biology Vol 111 November 1990 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with asparagine, did not affect biological activity while the replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (see Lazar et al Molecular and Cellular Biology Mar 1988 Vol 8 No 3 1247-1252).

In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance on the immunogenic activity of the variant peptide of SEQ ID NO:7 disclosed in the specification as-filed does not appear to provide sufficient written description for the genus of peptides encompassed by the claimed specificities in view of the above evidence, which indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.

For inventions in an unpredictable art, adequate written description of a genus, which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., Eli Lilly. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of variant peptides of SEQ ID NO:36, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddles v.Baird*, 30 USPQ2d 1481, 1483. In *Fiddles v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only an antibody generated against the isolated peptide of SEQ ID NO:7 (modified peptide of SEQ ID NO:36), but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 1-6, 13, 14 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-6 are interpreted as being drawn to antibodies or antigen-binding fragments thereof recognizing a peptide epitope in the MGFR region of MUC1 (Claim 1), where the antibody or antigen binding fragment thereof is bivalent (Claim 2) or monovalent (Claim 3), or where the peptide is PSMGFR (Claim 4), and the antibody or fragment of Claim 4 binds a peptide sequence of SEQ ID NO: 36, a functional variant or fragment thereof comprising up to 15 amino acid additions or deletions at the N-terminus and up to 20 amino acid substitutions (Claim 5), or a peptide sequence of SEQ ID NO: 36, a functional variant or fragment thereof comprising up to 10 amino acid substitutions (Claim 6). Claims 13 and 14 are interpreted as being drawn to a compostion comprising the antibody or fragment of Claim 1 (Claim 13) or a pharmaceutical composition of Claim 13 (Claim 14). Claim 17 is interpreted as being drawn to a kit comprising the antibody or fragment of Claim 1.

Bamdad teach bivalent and monovalent antibodies [0099; 0122; 0230] that bind to MGFR or modified MGFR [0056] or PSMGFR [0062] or fragments thereof [0277—278] of MUC1, diagnosing cancers with the antibody, for example[0133], and compositions comprising pharmaceutical compositions, and kits comprising the antibody [0011; 0143]. Because the claims broadly recite any antibody binding to any region within the MGFR domain of the MUC1 protein, and Bamdad et al. teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite

comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, the claims are considered to encompass an antibody binding to an unmodified sequence of SEQ ID NO:36, where zero modifications are read into the range.

14. Claims 1-6, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01).

The interpretation of the claims is discussed supra.

Kufe discloses on p. 2, line 16 an extracellular domain of MUC-1 protein comprising amino acid residues corresponding to SEQ ID NO:36 for the PSMGFR domain, antibodies against the PSMGFR domain in both monovalent and bivalent forms (pp. 10-14; p. 31), and pharmaceutical compositions (p. 26-29). Because the claims broadly recite any antibody binding to any region within the MGFR domain of the MUC1 protein inclusive of the PSMGFR domain, and Kufe teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, which corresponds to the peptide sequence for the PSMGFR domain of Muc-1 shown on p. 2, line 16 of Kufe, the claims are considered to encompass an antibody binding to an unmodified sequence of SEQ ID NO:36 (native PSMGFR), where zero modifications are read into the range.

15. Claims 1-6, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Wreschner et al. (US 20050019324; published 1/27/05; filed 3/26/02).

The interpretation of the claims is discussed supra.

Wreschner discloses an isolated antibody or fragment including monovalent and bivalent antibodies and fragments [0034; 0047], which specifically binds to an epitope in the extracellular region of an isoform of MUC1 protein [0019] where the epitope is located in the 15 amino acid sequence that resides at the N-terminal portion of the 59 amino acid segment which is located directly N-terminal to the transmembrane domain of the MUC1/Y, MUC1/X and MUC1/REP proteins [0044], a pharmaceutical composition comprising the antibody [0056]. Because the claims broadly recite any antibody binding to any region within an MGFR domain of a MUC1 protein inclusive of the PSMGFR domain and the specification defines these domains as extracellular domains, and Kufe teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, which corresponds to the peptide sequence for the extracellular domain of Muc-1 described in Wreschner, the claims are considered to encompass an antibody binding to an unmodified sequence for the extracellular (SEQ ID NO:36 (native PSMGFR)), where zero modifications are read into the range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01) in view of Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07).

The interpretation of Claims 1 and 17 is discussed supra.

The kit comprising the antibody or binding fragment that specifically binds to MGFR was prima facie obvious at the time of the invention over Kufe and Bamdad.

The interpretation of Kufe and Bamdad is discussed supra. Kufe appreciates compositions for administering as therapies or as diagnostics but does not disclose a kit comprising the anti-MGFR antibody as does Bamdad.

It would have been prima facie obvious to have produced a kit comprising the antibody of the invention and one would have been reasonably assured of success in having done so at the time of the invention based on Kufe and Bamdad. Both Kufe and Bamdad disclose antibodies recognizing different domains on the MUC1 protein, and more especially those recognizing the sequence TINVHDVETQFNQYKTEAASRYNLTISDVSVSDVPFPFSAQSGAG found in the extracellular domain of MUC1 protein. Both Kufe and Bamdad disclose compositions comprising the antibody for detecting the region of interest on the MUC1 protein, where such detection methods would have provided motivation to formulate the antibody into a kit. Specifically, Bamdad teaches such kits, and therefore one of skill in the art would have been reasonably assured of success in having produced a kit for the antibody of the invention because identical kit/antibody combinations had been disclosed in the art at the time of the invention. For these reasons the kit comprising the anti-MGFR antibody or a binding fragment thereof would have been prima facie obvious.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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